ORIGINAL ARTICLE

Compression therapy in 100 consecutive patients with venous leg ulcers

Évaluation de la compression chez des patients souffrant d’ulcères de jambe à prédominance veineuse : étude observationnelle chez 100 patients consécutifs


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KEYWORDS
Leg ulcer; Compression; Adherence; Education program

Summary
Objective. — To evaluate compression therapy for venous leg ulcers in terms of adherence, acceptability, quality, and effectiveness.
Design of study. — Prospective observational cohort study.
Subjects. — One hundred consecutive patients with active or healed leg ulcers and chronic lower limb venous insufficiency stage C5 or C6 in the CEAP classification scheme.
Interventions. — Compression systems applied in a community-based practice.
Main outcome measures. — A standardized form was used to collect: (1) data on patient adherence; (2) objective criteria evaluating the quality, effectiveness, and correct application of compression systems and; (3) patient education and perceptions about their compression therapy.
Results. — Patient adherence with compression therapy was high (89%), even though it was often a source of discomfort. Only 10% of patients signaled no discomfort. Drawbacks reported by patients were excessive warmth (29%), pruritus (33%), unacceptably high cost (48%), and moderate to considerable difficulty putting on footwear (64%). In the 11% of patients who did not wear their compression system, reasons for nonadherence were inadequate comprehension of expected benefits (45.5%), pain related to compression (36.4%), difficulty applying the compression system (27.3%), and difficulty putting on footwear (27.3%). Application was correct in 51.7% of adherent patients; errors in the remaining patients included slippage, failure of the bandage to extend to just under the knee (55.8%), a tourniquet effect (21%), failure of the bandage to extend to just under the knee (55.8%), a tourniquet effect (21%), failure of...
Compression therapy in 100 consecutive patients with venous leg ulcers

253

Introduction

Leg ulcers constitute a major public health burden. The estimated prevalence of leg ulcers in the general population is 0.045% to 0.63% and increases with age to 5% after 80 years [1]. Leg ulcers generate substantial healthcare costs. In the UK, leg ulcer care is estimated to cost 330 to 661 million euros annually [2].

Compression therapy plays a key role in the treatment of patients with venous leg ulcers, both for the healing of open lesions and for preventing recurrences [3,4]. It is also the main treatment of post-thrombotic syndrome, which is largely used by physicians [5]. Thus, compression therapy has a very prominent position in published recommendations on the management of predominantly venous leg ulcers [1,6,7]. Compression decreases the elevated pressure within the venous system and may also increase arterial blood flow according to recent data in patients with mixed ulcers [8].

To be effective, compression bandages must be worn continuously, properly applied, made of good quality material, and changed regularly. In addition, the pressure applied must be sufficient (30mmHg at the ankle at bandage application) [9]. Ten published studies of compression bandaging indicate that patient adherence varies widely. Thus, poor adherence has been reported in 10% to 80% of patients and has shown to be associated with a 2-fold increase in the time...
of ulcer healing [10]. We are not aware of any studies that simultaneously evaluated adherence, effectiveness, quality, and acceptability of compression bandaging.

The objective of this prospective observational cohort study was to evaluate compression bandaging in terms of adherence, acceptability, quality, and effectiveness in patients with venous leg ulcers in France.

Patients and methods

Study population and study design

A prospective observational cohort study was conducted in 100 consecutive patients with venous leg ulcers and chronic venous disease of the lower limbs stage C5 or C6 in the CEAP classification scheme. All study patients were evaluated by the same physician at the vascular diseases outpatient clinic of the Saint-Joseph Hospital in Paris, France.

Patients were eligible if they had leg ulcers due only to venous disease, predominantly to venous disease (ankle brachial index between 0.7 and 0.9), or to multiple factors among which venous disease played a major part. Patients could be enrolled at their first visit or during follow-up visits in the vascular diseases clinic. To ensure that included patients would be able to provide the information needed for the study, we only included patients who were free of cognitive disorders. Compression bandages were applied in a community-based practice.

Evaluation

General study data

The study data were collected on standardized forms. The following were recorded: age, sex, body mass index (BMI), and duration of follow-up by a vascular diseases specialist. In all patients, the superficial arteries were palpated, the ankle brachial index was measured, and Doppler ultrasonography of the superficial and deep leg veins was performed. The ulcers were described based on the following features: open or healed, location(s), etiology, surface area measured using the Visitrak® grid and digital tablet, and factors of adverse prognostic significance, namely, duration longer than 6 months and surface area greater than 10 cm²[11,12].

Prescription and nature of compression therapy

Detailed information on compression bandaging was obtained from each patient. The following were recorded: whether compression bandaging was first prescribed by a primary care physician or by a vascular physician; whether the bandages were applied by the patient, a family member, a general nurse, or a specialized nurse; and frequency of bandage application. The bandages were described as single layered or multilayered and as short-stretched or long-stretched and the compression hosiery as knee-high, thigh-high, or pantyhose. The class of compression stockings was recorded, as well as whether the patient used a donning aid.

Patient adherence, application technique, quality of material, and effectiveness

Patient adherence with compression therapy was assessed by determining whether the patient wore the bandages and/or hosiery. The following reasons for nonadherence were sought: difficulty wearing shoes, pain, difficulty applying the bandages or putting on the hosiery, and lack of understanding of the benefits of compression therapy.

The quality of bandage application technique was evaluated. Compression bandages were classified as correctly applied if they started at the base of the toes, included the heel, and were wound in regular spirals along the entire leg to just under the knee. The following errors were sought: tourniquet effect; bandage stopping too low on the leg, not starting at the base of the toes, or not including the heel; bandage not sufficiently tight; irregular spirals; and slippage.

The condition of the bandage material was assessed by recording soiling, tears or holes, and distortion. We also recorded whether the bandages were replaced every 3 months as recommended by most manufacturers.

Compression therapy was considered effective if there was no discharge visible through the bandage or hose and if the edema was controlled. Any discharge visible through the compression bandage or hose was noted. Complete resolution of the edema was defined as absence of edema at the foot, ankle, and calf. Both calves were measured for purposes of comparison.

Finally, compression therapy use was considered adequate if the compression bandage or hose was worn by the patient, properly applied and effective.

Patient education and perceptions about compression therapy

Patient education about compression therapy was evaluated using three questions: one about the reason for compression therapy (examples of correct answers were edema, poor venous circulation, varices, and ulcer), one about the mechanism of action of compression therapy (correct answers included helping the ulcer to heal, preventing ulcer recurrence, improving venous return, and decreasing the edema), and one on the requirements for compression bandaging (starting at the base of the toes, including the heel, winding up to the knee in regular spirals; wearing short-stretch bandages 24 h a day; and wearing hosiery and long-stretch bandages every day from the moment you wake up in the morning to the moment you go to bed at night).

Patient perceptions of compression therapy were recorded. Patients used a 0–10 visual analog scale (VAS) to score compression-related pain, if present. Unpleasant sensations such as pruritus or excessive warmth were recorded. Patients were asked about the ease of wearing their shoes, perceived cosmetic issues, acceptability or unacceptability of the cost, and the extent to which they felt helped by compression therapy. Acceptability was scored by the patients on an overall scale ranging from 0 (unacceptable, uncomfortable, very burdensome) to 10 (very easy to wear; improves comfort and relieves symptoms, cannot do without).
Comparison of patients seen by general practitioners and by vascular specialists

We compared patients followed up by primary care physicians (i.e., enrolled in the study at their first visit to our vascular diseases clinic) and those followed up by a vascular diseases specialist (i.e., already seen previously at least once at a vascular diseases clinic for the leg ulcer), in terms of adherence, application, and patient education.

Statistical analysis

The chi² test was used to compare patients followed up in community practice and those followed up at the vascular diseases outpatient clinic.

Results

Of the 100 study patients, 89 adhered to their compression therapy regimen.

General patient characteristics

There were 60 women and 40 men with a mean age of 74.5 years (range, 36—91) and a mean BMI in the overweight range (28.8 kg/m²; range, 17—55.1), in keeping with earlier data [13,14]. Of the 100 patients, 15 were enrolled in their first visit at the vascular diseases clinic and 85 during subsequent visits.

The features of the 100 ulcers are reported in Table 1. Most of the ulcers (91%) were open, as expected, as patients usually discontinue their vascular diseases clinic visits once their ulcers have healed. Some of the ulcers were multifocal. The assessment of factors predicting difficult ulcer healing showed that ulcer surface area was greater than 10 cm² in 41.8% of cases and that 64.8% of the open ulcers had been present for more than 6 months.

Prescription and nature of compression therapy

Table 2 details the compression therapy regimens used by the 89 treatment-adherent patients. Among these 89 patients, 15 (16.8%) used class I or II hosiery, eight (9%) used class III or higher hosiery, 38 (42.7%) used single-layer bandages, and 28 (31.5%) used multilayer bandages.

Of the 100 patients, 15 had their compression therapy prescribed by a primary care physician and 85 by a vascular physician.

Patient adherence, application technique, quality of material, and effectiveness

The proportion of adherent patients was 89% overall, 100% among patients with healed ulcers (n = 9), and 87% among patients with open ulcers (n = 80). The most common reason for not wearing the compression bandages or hose (11 patients) was inadequate patient education (n = 5, 45.5%), followed by technical difficulties applying the bandages or putting on the hose (n = 4, 36.4%) and by pain due to the compression (n = 3, 27.3%).

Of the 89 treatment adherent patients, 29 (32.6%) applied the compression themselves, four (4.5%) had the compression applied by a family member, and 56 (62.9%) had the compression applied by a registered nurse. Only two (8.7%) patients who wore compression hose used a donning aid. The compression bandages or hose were changed every 24 h for 47 (52.8%) patients, every 48 h for 38 (42.7%) patients, and at longer intervals for four (4.5%) patients. The prescription was misunderstood by four patients, two of whom wore the hose over the bandages and two who wore only a cohesive bandage.

Overall, compression strength complied with the international recommendations (multilayer bandages or class III hose) in 36 (40.5%) patients.

Compression was applied correctly in 46 (51.7%) patients and incorrectly in 43 (48.3%). Numerous errors in bandage and hose application were recorded, with the most common being bandage slippage and failure to include the heel (Table 3). In the group using bandages, application by general nurses was correct in 12 (32.4%) cases, application by specialized nurses in 10 (52.6%) cases, and application by patients in four (40%) cases. None of the patients had their bandages applied by family members.

The compression material was of good quality and had been changed within the last 3 months in 70 (78.7%) of the 89 treatment-adherent patients. In the remaining 19 (21.3%), the material was of poor quality: excessive hosiery wear was noted in five (26.3%) and holes in six (31.6%) patients, the bandages were distorted in six (31.6%) patients and cut in one (5.3%) patient, and the material was soiled in 12 (63.2%) patients.

A discharge was visible through the hose or bandage in 14 (17.5%) of the 80 treatment-adherent patients with open ulcers. The mean calf circumference difference showed that the calf on the side of the ulcer was 0.67 cm larger (range, −6 to +8 cm); however, this

<table>
<thead>
<tr>
<th>Type</th>
<th>Venous (40%)</th>
<th>Mixed (predominantly venous) (13%)</th>
<th>Multifactorial (predominantly venous) (47%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healed (9%)</td>
<td>5 (5%)</td>
<td>1 (1%)</td>
<td>3 (3%)</td>
<td>9</td>
</tr>
<tr>
<td>Open (91%)</td>
<td>35 (35%)</td>
<td>12 (12%)</td>
<td>44 (44%)</td>
<td>91</td>
</tr>
</tbody>
</table>
Table 2  Types of compression therapy used by the 89 treatment-adherent patients.

<table>
<thead>
<tr>
<th></th>
<th>Open ulcers (n = 80)</th>
<th>Healed ulcers (n = 9)</th>
<th>Total (n = 89)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hose</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>3</td>
<td>0</td>
<td>3 (3.3%)</td>
</tr>
<tr>
<td>Class II</td>
<td>10</td>
<td>2</td>
<td>12 (13.5%)</td>
</tr>
<tr>
<td>Class III or higher*</td>
<td>6</td>
<td>2</td>
<td>8 (9%)</td>
</tr>
<tr>
<td>Total</td>
<td>19 (23.8%)</td>
<td>4 (44.4%)</td>
<td>23 (25.8%)</td>
</tr>
<tr>
<td><strong>Single-layer bandage</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-stretch</td>
<td>5</td>
<td>2</td>
<td>7 (7.9%)</td>
</tr>
<tr>
<td>Short-stretch</td>
<td>27</td>
<td>2</td>
<td>29 (32.6%)</td>
</tr>
<tr>
<td>Cohesive</td>
<td>1</td>
<td>1</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>33 (41.2%)</td>
<td>5 (55.6%)</td>
<td>38 (42.7%)</td>
</tr>
<tr>
<td><strong>Multilayer bandage</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 long-stretch + 1 cohesive bandage</td>
<td>0</td>
<td>0</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>1 short-stretch + 1 cohesive bandage</td>
<td>16</td>
<td>0</td>
<td>16 (18%)</td>
</tr>
<tr>
<td>1 short-stretch + 1 stocking</td>
<td>2</td>
<td>0</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>2 long-stretch bandages</td>
<td>0</td>
<td>0</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>2 long-stretch bandages</td>
<td>6</td>
<td>0</td>
<td>6 (6.7%)</td>
</tr>
<tr>
<td>2 short-stretch + 1 cohesive bandage</td>
<td>3</td>
<td>0</td>
<td>3 (3.3%)</td>
</tr>
<tr>
<td>Profore*</td>
<td>1</td>
<td>0</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>28 (35%)</td>
<td>0</td>
<td>28 (31.5%)</td>
</tr>
</tbody>
</table>

* Class III or higher compression can be achieved by layering stockings, in which case we defined the class as the sum of the classes of each stocking.

* Profore® was the only multilayer compression bandage kit marketed in France at the time.

Finding was not interpretable, as some patients had muscle wasting in the same leg. The edema was fully controlled by compression therapy in 46 (51.7%) treatment-adherent patients overall, 8 (88.9%) with healed ulcers, and 38 (47.5%) with open ulcers. Among the patients with uncontrolled edema (n = 43, 48.3% of treatment-adherent patients), 32 (74.4%) used single-layer bandages or class I or II hosiery, which was incorrectly applied in 32 (74.4%) cases.

Compression therapy was considered adequate (worn, correctly applied, and effective) in 44 (49%) of the 89 treatment-adherent patients. Among these patients, 24 (54%) had a compression therapy regimen that complied with recommendations.

Patient education and perceptions about compression therapy

The patients reported numerous drawbacks of compression therapy, including excessive warmth (29%) and pruritus (33%). The cost of the compression material was considered unacceptable by 48% of patients, and finding appropriate footwear was described as fairly difficult to very difficult by 64% of patients. Only 10% of patients reported no drawbacks of compression therapy. Nevertheless, 78% of patients believed that compression therapy was useful and the overall acceptability score was high, at 7.2/10.

Finally, 79% of patients were able to explain why they needed compression therapy. However, 44% did not know the mechanism of action and 43% were not aware of the proper wear modalities.

Comparison of patients seen by general practitioners and by vascular specialists

Adherence was significantly greater among patients seen by vascular disease specialists (93% vs. 67%, \( P < 0.01 \)).

Among patients seen by vascular disease specialists (n = 85), 49 (58%) knew the mechanisms of action of compression therapy, compared to seven (47%) of those seen by primary care physicians. Corresponding proportions for knowledge of the modalities of compression therapy used were 51 (60%) and six (40%), respectively. These results were not significant.

Compression therapy was adequate (worn, correctly applied, and effective) in a significantly higher proportion of patients seen by vascular disease specialists (53.2% compared to 31.5% for general practice patients).
Compression therapy in 100 consecutive patients with venous leg ulcers

vs. 20% of patients seen by primary care physicians, \( P < 0.05 \).

**Discussion**

Adherence was good in our study, with 89% of patients wearing their compression material overall. Adherence was significantly better among patients seen by vascular disease specialists than among those seen by primary care physicians.

Adherence was higher in our study than in previous reports; thus, adherence rates ranged from 10% to 80% in a 2009 systematic review of compression therapy [10] and adherence was only 37% in a large study of compression stockings [15]. The good adherence rate in our population may be attributable to the patient recruitment at a single specialized center. In addition, good adherence among patients referred for the first time by primary care physicians may reflect selection bias, with referring physicians being aware of the treatment requirements in patients with venous leg ulcers.

The main reason for nonadherence in our study was poor understanding of the benefits of compression therapy (45% of nonadherent patients). The next most common reasons were difficulty applying the compression material, difficulty putting on footwear, and pain related to the compression. A systematic literature review published in 2009 [16] identified 31 studies of reasons for nonadherence to leg ulcer treatments, which included compression material, regular physical activity, and leg elevation when in the recumbent position. The heterogeneity of the studies precluded the obtaining of numerical data. The reasons for nonadherence were diverse and included pain, discomfort, and lack of education about compliance, in keeping with our findings. However, in a recent randomized controlled study, wearing compression bandages was associated with pain relief [17].

Therapeutic education is crucial to patient adherence with prescribed treatments. We found evidence that lack of therapeutic education was a major reason for nonadherence. Of the 100 patients, nearly half were unaware of the mechanisms of action and modalities of wear of the compression material (although most were adherent). In a study from the UK [14], an education program had no significant effect on adherence to compression therapy for venous leg ulcers. However, the sample size was small and the education program excessively complicated.

Many patients report adverse effects of compression therapy on quality of life [10]. In one of the few studies that evaluated this issue [18], the main complaints were discomfort, difficulty applying the compression, poor cosmetic appearance, and compression-related pain. These drawbacks may lead to nonadherence. Thus, in a study of compression stockings, they were the reason for nonadherence in one fourth of cases [15]. Similarly, in our study, the most common reasons for nonadherence after inadequate patient education were difficulties with compression application, difficulties with footwear, and compression-related pain. Only 10% of patients reported no drawbacks of compression therapy. Despite these drawbacks, 80% of patients felt that compression therapy was useful. We agree with Partsch [19] that improvements are within reach. Materials associated with better tolerance could be developed. The proportion of patients who used donning aids was only 8.7% in our study and could be increased. There is room for improvement in terms of the cosmetic appearance (color and texture) of compression hosiery. Finally, pain should be evaluated and treated before the initiation of compression therapy.

The cost of compression systems is another potential reason for nonadherence [20]. In France, compression systems are only partly reimbursed by the public health insurance system. Although over half of our patients felt that the cost of their compression systems was unacceptable, cost was not a reason for nonadherence. Nearly 80% of our patients had changed their compression system within the past 3 months, and none of the nonadherent patients ascribed their behavior to cost issues.

Bandage application technique was inadequate in nearly half the patients. Only about 30% of general nurses and 50% of specialized nurses applied the bandages correctly. These findings indicate inadequate awareness among physicians and nurses of proper technique in compression system application. Technical errors can be avoided by prescribing compression hosiery. According to a 2009 meta-analysis of randomized controlled trials, stockings were more effective than bandages [21]. However, the mean patient age in this study was 60 years, compared to 74 years in our population. This point is relevant, as older patients often experience difficulty in putting on firm-support stockings over ulcer dressings.

In our study, compression therapy was considered effective if the edema was controlled (no edema at the foot, ankle, or calf) and no discharge was visible on the bandage or hose. The edema was controlled in nearly 90% of patients with healed ulcers, as expected. In contrast, nearly half the patients with open ulcers had uncontrolled edema, indicating that the pressure applied was probably inadequate. According to the international recommendations concerning the management of venous leg ulcers, multilayered bandage or class III stockings should be used. The proportion of patients whose compression therapy complied with recommendations was significantly larger in the group without edema than in the group with edema (52% vs. 25%, respectively; \( P < 0.02 \)). This finding supports international recommendations and agrees with recent data showing better efficiency with multilayered than with single-layer compression [22].

We define adequate compression therapy as a compression system that was worn by the patient, correctly applied, and effective. Among the adherent patients (89/100), nearly half met these criteria overall, and the proportion was significantly higher in the group seen by a vascular diseases specialist than in the group seen in primary care (53% vs. 20%). However, these findings indicate a need for improvement.

The limitations of our study include recruitment bias due to the recruitment of our patients at a vascular diseases clinic. Thus, only 40% of the leg ulcers were caused by chronic venous insufficiency alone, compared to 70% in earlier studies [1]. Multifactorial ulcers with a predominantly
venous component accounted for 47% of all ulcers. Finally, most of the patients had factors of poor prognostic significance (ulcer duration longer than 6 months and/or surface area greater than 10 cm²).

Conclusion

We report the first data from France on adherence, quality, and acceptability of compression therapy for venous leg ulcers. Our study obtained strong evidence of insufficient education about compression therapy among physicians, nurses, and patients. Insufficient education is a key factor in incorrect compression system application and in patient nonadherence to compression therapy. Although the adherence rate was high in our study, effectiveness was inadequate in half the patients, as a result of insufficient pressure and errors in application. The main reasons for patient nonadherence were insufficient knowledge of the benefits of compression therapy and discomfort associated with the compression system. To improve compression therapy, educational programs designed for patients and healthcare professionals are needed.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References